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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/677,857 | 10/03/2003 | Eugene R. Cooper | 029318-0981 | 4616 |

31049 7590 07/08/2009

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| EXAMINER | |
|---|---|
| UNDERDAHL, THANE E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1651 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 07/08/2009 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/677,857 | COOPER ET AL. | |
| | Examiner | Art Unit | |
| | THANE UNDERDAHL | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *11,12 and 18-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 13-17, 56 and 57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/21/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**Detailed Action**

This Office Action is in response to the Applicant's reply received 4/21/09. Claims 1-57 are pending. Claims 11, 12 and 18-55 are withdrawn. No Claims are cancelled. No Claims 1, 3, and 57 have been amended. No Claims are new. Claims 1-10 and 13-17, 56 and 57 are considered in this Office Action.

**Response to Applicant's Arguments— 35 U.S.C § 103**

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) or 102(a) (b) (c) rejection of claims 1-10 and 56 and 57 over Ramirez et al. (U.S. Patent # 5632996) in view of Self (U.S. Patent # 4917816) were considered but not found persuasive.

The Applicant argues that the composition of Ramirez does not have "at least one surface stabilizer associated with the surface of the benzoyl peroxide particles" (Applicant's Response, pg 16). The Applicant argues that since the alkylbenzoate is used as a solvent it is not a surface stabilizer. First the Applicant has ignored that the Examiner has already cited colloidal silicon dioxide in the rejection as a surface stabilizer, which meets the limitations of dependant claim 10 thus must meet the limitations of claim 1. Also the Applicant has not provided a clear definition in their specification that would exclude alkylbenzoate (**AB**) as a possible surface stabilizer. Furthermore the picture provided by the Applicant is not commensurate with the scope of the claims. Indeed the claims read that the "surface stabilizer associated with the surface of the benzoyl peroxide particles" (Claim 1). Indeed the plain use term "associated" is broad. One of ordinary skill in the art would construe that if the compounds are simply in the same proximity they are "associated" when considering common use definitions. The claims do not limit that the surface stabilizer is a specific distance from the benzoyl peroxide (**BP**) particles or is bound via a particular force such

as van der Walls forces or otherwise integrated with particle. Indeed one of ordinary skill in the art would recognize that a solvent such as the Applicant proposes AB to be would inherently be associated with the surface of BP particles since these very particles are suspended or stabilized in the solvent.

The Applicant argues that there is no motivation to combine Ramirez et al. with Self et al. since Ramirez et al. is drawn to anhydrous compositions of BP while Self et al. is drawn to water dispersions of BP. However the Applicant's attention is drawn to column 4 for Ramirez et al. that teach an acne lotion that contains over 60% water. Therefore this assertion that Ramirez et al. only teach anhydrous BP compositions is expressly contradicted. It is acknowledged in M.P.E.P. § 2143.01, that the prior art as a whole must suggest the desirability of the invention, but a finding that the prior art as a whole suggests the desirability of a particular combination need not be supported by a finding that the prior art suggest that the combination claimed is the preferred, or most desirable combination. The prior art's mere disclosure of more than one alternative does not constitute a teaching away from the claimed invention because such disclosure does not criticize, discredit, or other wise discourage the solution claimed in the patent application. See In re Fulton, 391 F.3d 1195, 73 USPQ2d 1411 (2004).

The Applicant argues that the removal of the word "about" concerning the size of the BP particles overcomes the art of Self. However Self still teaches that the particle sizes are 2 microns which obviously reads on the claimed invention. Furthermore as stated in previous Office Actions, the size of a particle is a well known variable that is optimizable and obvious unless the Examiner is provided evidence to the contrary

(M.P.E.P. § 2144.05) that the size is indeed critical to the invention (M.P.E.P. § 2144.05, III "Applicants can rebut a prima facie case of obviousness based on overlapping ranges by showing the criticality of the claimed range") such as new and unexpected results.

Therefor the rejection stands and is repeated below.

Claims 1-10, 56 and 57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez et al. (U.S. Patent # 5632996) in view of Self (U.S. Patent # 4917816).

These claims are drawn to a composition comprising particles of benzoyl peroxide (**BP**) or a salt thereof that is present in an amount from about 99.5% to about 0.001% by weight, wherein the particles have an average size of less than 2000 nm, and also contains a surface stabilizer is present in an amount of about 0.5% to 99.999% by weight. These particles can be in a crystalline phase, amorphous phase, a semi-crystalline phase, or a semi-amorphous phase. Claim 3 further limits claim 1 by requiring the BP particles be less than 1900 nm in size. Claim 4 limits the formulation of the composition in claim 1 to creams. The composition further comprises pharmaceutically acceptable excipients, carriers, or a combination thereof.

The surface stabilizer is selected from the group of non-ionic surface stabilizers. Claim 9 further limits that the composition of claim 1 comprises at least two surface stabilizers. Claim 10 provides a list to limit the surface stabilizers, some of which are ionic and non-ionic.

The Examiner notifies the Applicant that the use of "about" has a larger scope than the numbers that confine the size or amount of BP crystals in the composition. As such teachings of a range being about less than about 1900 nm or 2000 nm or even about 99.5% to about 0.001% are much broader than the numbers specify. "About", as the Examiner interprets, adds both to the upper and lower limitations of a range, since in common use terms "about" does not limit a value in one direction. For example, a pH of "about" 7 can reasonably be interpreted by as skilled artisan as 7.5 or 6.8.

Ramirez et al. teach a composition of BP that ranges from 70% to 5% by weight and a surface stabilizer of alkylbenzoate (**AB**) that ranges in the composition form 95% to 30% by weight (col 3, lines 50-65, and col 2, lines 59-68). These BP compositions can be formulated into a lotion, cream or gel (lines 29-31) or a solid dosage form such as a soap for use on the skin. The cream compositions contain other non-ionic surface stabilizers such as AB as well as colloidal silicon dioxide (col 4, line 40). The cream also contains pharmaceutically acceptable excipients and carriers such as glycolic acid and petrolatum (petroleum jelly).

Ramirez et al. also teach that their amorphous powder of BP is an art-defined equivalent to BP crystals in a cosmetic composition (col 3, line 28-46). Therefore it would be obvious for one of ordinary skill in the art to substitute one crystal phase of BP for another in a cosmetic formulation (M.P.E.P. § 2144.06).

Ramirez addresses particle size as important in the formulation by teaching "It would be desirable to provide a BP compositions…which have a smooth texture appropriate for cosmetic products" (col 1, lines 53-59) and BP "crystalline powder is

gritty" and discusses the importance to "prepare a paste having benzoyl peroxide crystals that are sufficiently fine to be of acceptable texture for preparing products for topical use" (col 1, lines 30-40). Therefore in light of the teachings if Ramirez et al. one of ordinary skill in the art would recognize the importance of crystal size in the texture of a BP composition, and that finer crystals are required to reduce the grittyness of the composition to make it acceptable for topical use. Therefore, one of ordinary skill in the art would be motivated to use small BP crystals from the teachings. However, Ramirez et al. does not teach the specific particle size of the BP in their composition as limited in the claims. However this would be obvious in view of Self et al.

Self et al. teaches small BP crystals of "from about 2 microns" (Self, col 9, line 14) as "active ingredients in dermicidal and other pharmaceutical compositions" (Self, col 3, lines 62-63). "About 2 microns" obviously meets the limitations of about 1900 or about 2000 nm as mentioned in the preceding paragraphs.

Therefore one of ordinary skill in the art would be motivated by both Ramirez et al. to use the BP crystals of Self et al. since Ramirez et al. desires the use of fine crystals in their skin compositions and Self et al. teach that their BP crystals are useful in dermicidal (skin) compositions. Furthermore, since both teach BP crystals one of ordinary skill in the art would recognize that it would be obvious to substitute the crystals of Self et al. in the composition of Ramirez et al. with reasonable expectation of success since both BP crystals have the same chemical composition and are both used in skin compositions ((KSR International v. Teleflex Inc. 550 U.S. ___, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007)).

Therefore the references listed above renders obvious claims 1-10 and 56 and 57.

In the response submitted by the Applicant, the 35 U.S.C § 103 (a) of claims 1-10 and 14-16, 56, 57 over Ramirez et al, Self in further view of Kanios et al. were considered but not found persuasive. Also the 35 U.S.C § 103 (a) of claims 1-10 and 13-17, 56, 57 over Ramirez et al, Self, Kanios in further view of Bartnick et al. were considered but not found persuasive.

Applicants rely on the arguments used in traversing Ramirez et al. in view of Self to also traverse these rejections without additional arguments. However, as explained above, the previous rejections stand. Therefore, the response set forth above to arguments also applies to these rejections.

Claims 1-10 and 14-16, 56, 57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez et al. (U.S. Patent # 5632996) and Self (U.S. Patent # 4917816) as applied to claim 1-10 above, and further in view of Kanios et al. (U.S. Patent # 5719197, 1998).

Claims 1-10 and new claims 56 and 57 are summarized above. Claims 14-16 further limit the composition of claim 1 by requiring the composition to be a bioadhesive, additionally comprise one or more non-BP active agents selected from the group of nutraceuticals, retinoic acid, antibiotics, sulfur and salicylic acid.

As mentioned above Ramirez et al. and Self et al. render obvious claims 1-10 above by teaching a BP composition with a several surface stabilizers that can be formulated into a cream for cleansing the skin (col 1, lines 10-13) which includes acne treatment (col 4, lines 55-60). However they do not teach the components of claims 13-17. These are taught in the by Kanios et al. Kanios et al. teach that their composition for topical applications of pharmaceutical agents and bioadhesive carriers can be formulated into an anti-acne composition containing BP and the additional active agent retinoic acid.

Since the anti-acne compositions of Ramirez et al. and Kanios et al. share common components to treat a common goal it would be obvious for one of ordinary skill in the art to add the composition of Ramirez et al. in view of Self et al. to the invention of Kanios. The motivation and reasonable expectation of success is provided by Kanios et al. who teach an anti-acne composition with similar components to Ramirez et al. Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1-10 and 14-16, 56, 57 are not allowable.

Claim 1-10 and 13-17, 56, 57 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez et al., Self et al. and Kanios et al. as applied to claims 1-10 and 14-16, 56 and 57 above, and further in view of Bartnick et al. (U.S. Patent # 5,399,353, 1995).

Claims 1-10 as well as 14-16 are summarized above. Claim 13 further limits the composition of claim 1 by requiring the surface stabilizer is lysozyme, polyvinylpyrrolidone (**PVP**), benzalkonium chloride (**BKC**). Claim 17 limits the antibiotic to clindamycin or erythromycin.

Claims 1-10 are rendered obvious by Ramirez et al. in view of Self et al. Claims 1-10 and 14-16 are rendered obvious by the combination of Ramirez et al., Self et al. and Kanios et al. While Kanios et al. does teach the addition of antibiotics clindamycin and erythromycin as well as lysozyme and PVP to their composition the motivation to add these components to a skin cleansing composition is provided by Bartnick et al.

Bartnick et al. teach a composition to disinfect undamaged skin (col 7, lines 15-20). In this composition they include strong disinfectants such as BP, lactic acid as well as PVP and lysozyme (col 7 line 65 to col 8 line 2). Ramirez et al. already adds the disinfectants lactic acid and BP to their composition (col 4, lines 35-45) and M.P.E.P. § 2144.06 states

> "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art."

Therefore it is *prima facie* obvious to one of ordinary skill in the art to add more disinfectants to the composition of Ramirez et al., Self et al. and Kanios et al. as motivated by Bartnick et al.

Bartnick et al. also teach the addition of antibiotics to a composition to clean skin (col 7, line 62). Bartnick et al. is silent on which antibiotic. However Kanios et al. teach that the antibiotics clindamycin and erythromycin can be added to their skin composition (col 16, lines 63-65). One of ordinary skill in the art would recognize that antibiotics would be useful in treating skin diseases cause by bacterial infections such as acne. It would therefore have been obvious for the person of ordinary skill in the art to add the antibiotics of Kanios to the combined composition of Ramirez et al., Self et al. and Kanios et al. The motivation is provided by Bartnick et al. who teach the additional components of a skin cleansing composition and the reasonable expectation of success is provided by the formulations of Kanios et al. Therefore, the invention as a whole would have been prima facie obvious at the time of filing in view of the references listed above and as such claims 1-10 and 13-17, 56, 57 are not allowable.

In summary no claims, as written, are allowed for this application.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure**, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached at (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651